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APPLICATION NO.	FILING DATE	[illegible]	[illegible]	[illegible]
09/770,107	01/24/2001	Joanne M. Meyer	3322.01E01	5567

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/770,107	Applicant(s) MEYER et al.
	Examiner Cynthia B Wilder	Art Unit 1637

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE X 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Sep 5, 2002*.

2a) ☐ This action is **FINAL**. 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-43 and 54-62* is/are pending in the application.

4a) Of the above, claim(s) *21-43, 56, and 59* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *1-20, 54, 55, 57, 58, and 60-62* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)	Notice of References Cited (PTO-892)	4)	Interview Summary (PTO-413) Paper No(s).
2)	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5)	Notice of Informal Patent Application (PTO-152)
3) X	Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5 and 7*	6)	Other:

DETAILED ACTION

1. Applicant's preliminary amendment along with correction of drawing filed in 10 is acknowledged. Claims 44-53 have been canceled. Claims 54-62 have been added. Claims 1-43 and 54-62 are pending.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-20 and 54-62 in Paper No.12 is acknowledged. The traversal is on the ground(s) that Applicant believes that Group I and II should be examined together pursuant to 35 USC 103(b)(2), under which a patent issued on a biotechnological process shall also contain claims directed towards the composition of matter utilized by that process. Applicant contends that Group I and II do not define products and methods for using such products with biological properties which are distinct or which warrant separation of examination and searches. Applicant request the claims of Group I and II be rejoined. With respect to the election of a nucleic acid sequence from SEQ ID NOS: 1 , 4 and 33-127, Applicant contends that the election is properly a species election and are not patentably distinct species. Applicant states that SEQ ID NO: 1 is a cDNA sequence of DISC1 polypeptide and SEQ ID NO: 4 is a large genomic DNA clone of contains a segment of human chromosome 1 which contains DISC1 and DISC2. Applicant states that each of SEQ ID NOS 33-43 represent a single nucleotide polymorphism and SEQ ID NOS: 44-127 represent oligonucleotide primers used to amplify DISC1 or DISC2 genomic sequences. Applicant states that all of the polymorphisms are linked by a single

inventive concept: that polymorphisms in the DISC1 gene (and hence, in its genomic sequences) co-segregate with neuropsychiatric disorders (for example schizophrenia) and can therefore be used to diagnose and/or treat such disorders. Applicant states that theses individual sequences represent separate species of Applicant's generic invention; namely, polymorphisms of the DISC1 gene that may be commonly used to diagnose and/or treat neuropsychiatric disorders. Applicant concludes that the restriction requirement is improper and should be withdrawn in favor of a species election requirement.

3. The arguments have been thoroughly reviewed and considered but they are not found persuasive for following reasons: First in response to Applicant's arguments that Group I drawn to the product and Group II drawn to the process of using the product are not patentably distinct, it is noted that the inventions can be shown to be patentably distinct if e.g. the process for product can be practiced with another materially different product or if e.g. the product can be used in a materially different process of using that product (MPEP 806.05(h)). As noted in the prior office action the claimed isolated nucleic acid and kit can be used in a materially different process besides those cited in the claims, such e.g., in methods of differential display or in methods of nucleic acid sequencing or in methods of nucleic acid purification or in methods of nucleic acid cloning or in methods of cassette mutagenesis, etc.

It is noted that pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), if the elected product claims are found to be allowable, claims directed to the process of making or using the patentable product, previously withdrawn from consideration as

a result of a restriction requirement will rejoined and fully examined for patentability under 37 CFR 1.104.

With respect to Applicant arguments concerning the sequence restriction requirement, it is noted each SNP is unrelated to each other SNP in that each of the SNPs differ in structure and effect from each other SNP. Specifically the chemical structure of any SNP is necessarily different from that of any other SNP because for example the nucleic acid sequence of SEQ ID NO: 33 as shown in Table 6 is chemically and structurally different from the nucleic acid sequence of SEQ ID NO: 35 shown in Table 6 (page 113 of specification). Likewise, the different SNPs may have different functional characteristics as well and differ in design, since they differ in structure. The specific requirement that the inventions are capable of separate use is clearly evident regarding the different sequences both by the separate claiming and because each SNP can be separately screened against the DISC genome.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-20, 54, 55, 57, 58, 60 -62 and SEQ ID NOS: 1, 33, 44 and 45 are discussed below. Claims 21-43, 56, 59, 61 and SEQ ID NOS: 4, 34-43 and 46-127 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101 Lack of Utility

4. Claims 1-20, 54, 55, 57, 58, 60-62 have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Application under 35 U.S.C. 112, first

paragraph, "Written Description" requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

> Credible Utility" - Where an Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

> "Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA.

> 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-20, 54, 55, 57, 58, 60-62 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed isolated nucleic acid and kit which comprises a nucleotide sequence of a polymorphic region of a DISC1 allelic variant, wherein the DISC1 allelic variant has a nucleotide sequence that differs from a reference nucleotide sequence selected from the group consisting of: (a) the nucleotide sequence set forth in SEQ ID NO: 1; (b) a DISC1 nucleotide sequence contained in the clone RP11-17H4, RP11-9801, RP4-58N17, RP5-865N13 or RP4-730B13 and the nucleotide and (c) the nucleotide sequence set forth in SEQ ID NO: 4 or wherein the nucleic acid is selected from the group consisting of SEQ ID NOS: 33-43 and complementary sequences thereof is not supported by a specific asserted utility because the disclosed use of the isolated nucleic acid molecule is not specific and is generally applicable to any nucleic acid molecule. For example, the specification at beginning at page 42 disclose the isolated nucleic acid molecule as useful as probes in hybridization reactions or primers in an amplification reaction to specifically identify variant forms of a gene, such as the genes recited in Table 5. These are all non-specific uses that are applicable to nucleic acids in general and are not particular or specific to the nucleic acids claimed.

The claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or gene product. For example, the specification teaches that the isolated nucleic acid is used as a probe to specifically identify allelic variant forms of a gene; specifically allelic variant of DISC1 and DISC2 genes, such as those recited in Table 5 at page 113 of the specification. The specification states that the variant form(s) of a gene as listed in the cited Table 5 correlate with the presence of a neuropsychiatric disorder, such as schizophrenia, schizo affective disorder, bipolar affective disorder, unipolar affective, and adolescent conduct disorder. The specification, however fails to provide any evidence that the claimed allelic variances identified are associated with any neuropsychiatric disorders. The specification appears to only speculates that the claimed allelic variants of the DISC1 gene are functional, since the DISC1 gene (from which the allelic variants have been isolated) is known to be associated with neuropsychiatric disorders. Hence, the need for further research is clearly necessary to determine the function of the claimed allelic variants as correlated with a neuropsychiatric disorder or a substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case the claimed isolated nucleic acid molecule does not have an asserted or identified specific and substantial utilities or the claimed variant being identified by the probe or primers of the instant invention. Identifying and studying the properties of a gene itself or the mechanisms in which the gene is involved does not define a "real world" context of use. In fact, it appears that the claim invention is only useful for identifying itself.

Similarly, the claimed use of identifying probes and primers to detect allelic variants of the gene with no asserted function is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claims 17-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-20, 54, 55, 57, 58 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to an isolated nucleic acid and kit which comprises a nucleotide sequence of a polymorphic region of a DISC1 allelic variant, wherein the DISC1 allelic variant has a nucleotide sequence that differs from a reference nucleotide sequence selected from the

group consisting of (a) the nucleotide sequence set forth in SEQ ID NO: 1; (b) a DISC nucleotide sequence contained in the cloned RP11-17H4, RP11-9801, RP4-584N17, RP5-865N13 or RP4-730B13; and (c) the nucleotide sequence set for in SEQ ID NO: 4. The claims as written encompasses a large genus of nucleic acid molecules from the DISC1 gene not described or disclosed. The specification discloses at page 114, Table 6, eleven polymorphic sequences of the DISC1 gene. However, the specification fails to discloses the many other polymorphic sequences of the DISC1 gene encompassed by the claims. The specification provides insufficient written description to support the genus encompassed by the claim.

A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species as claimed in claims 1-20, 54, 55, 57, 58, 60-62 of the specification fails to show that Applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Claim Rejections - 35 USC § 112 Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claims 1-20 and 54, 55, 57, 58, 60 -62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 1-20 and 54, 55, 57, 58, 60-62 are indefinite at DISC1 because abbreviations often have more than one meaning in the art. It is suggested inserting the full name of the abbreviation as support by the specification into the independent claims 1, 6, 19 and 54.

(b) Claims 6, 8, 19 and 57 are indefinite at "capable of" because it cannot be determined whether the limitation after "capable of" is a property of the probe and primer or separate entity. It is suggested changing "capable of hybridizing" to "which hybridizes" or some other positive, active language as supported in the specification.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

January 6, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
1/8/03